

REMARKS

The Present Invention

The present invention is directed to compounds comprising the Dmt-Tic pharmacophore, related compositions and methods of use.

The Pending Claims

Claims 1-20 are pending, with claims 11-18 withdrawn as directed to nonelected subject matter. Claims 1-9 and 19 are directed to the compounds, whereas claims 10 and 20 are directed to the compositions comprising such compounds, and claims 11-18 are directed to methods of use.

The Amendments to the Specification, Claims and Abstract

The specification was amended to include references to SEQ ID NOS., which are consistent with the Sequence Listing filed herewith. In addition, the specification was amended to correct typographical errors. In particular, the sequences for Deltorphan A and DPDPE were corrected, and the sequence listing reflects those corrections. These reagents are well-known in the art, and these changes do not constitute new matter. The abstract was amended to shorten the length as supported by the specification at, for example, page 1, lines 9-12. The claims have been amended to point out more particularly and claim more distinctly the present invention. In particular, claims 10 and 20 have been amended to recite that the composition comprises at least one compound of the present invention and a carrier, which is supported by the specification at, for example, page 15, lines 24-25. No new matter has been added by way of these amendments. Separate documents setting forth the amendments to the specification, claims, and abstract, as well as all of the pending claims are attached hereto.

The Office Action

The Office has objected to the length of the abstract. In addition, the Office requires the submission of a Sequence Listing. Finally, claims 10 and 20 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Reconsideration of the pending claims is hereby requested.

Discussion of the Objection to the Abstract

The abstract has been amended to shorten the length, thereby rendering the Office's objection moot.

Discussion of the Sequence Listing

In accordance with the requirements of 37 CFR 1.821-1.825, a sequence listing is being submitted herewith. The sequence listing is in the form of a paper copy and a computer-readable copy on a computer diskette. The undersigned hereby verifies that the content of the paper copy and the computer-readable copy, as concurrently being submitted, are the same as each other and as the sequences set forth in the specification as filed and corrected herein.

We note that the peptide sequence Tyr-Tic-Phe-(Phe) (see, e.g., page 26, line 21) is not included in the Sequence Listing, since the compound Tic is a β -amino acid and, therefore, is not required to be submitted in a Sequence Listing. Mr. Bob Wax in the Sequence Rules Office at the U.S. Patent and Trademark Office confirmed that β -amino acids do not need to be submitted in a Sequence Listing.

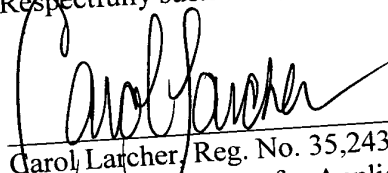
Discussion of the Rejection Under Section 112, Second Paragraph

Claims 10 and 20 have been rejected under Section 112, second paragraph, as allegedly indefinite. In view of the amendment of claims 10 and 20, this rejection is believed to be moot.

Conclusion

The application is considered to be in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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Date: December 21, 2001



PATENT
Attorney Docket No. 209897

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Lazarus et al.

Application No. 09/814,558

Art Unit: 1653

Examiner: D. Lukton

Filed: March 22, 2001

For: DMT-TIC DI-AND TRI-PEPTIDIC
DERIVATIVES AND RELATED
COMPOSITIONS AND METHODS
OF USE

**AMENDMENTS TO SPECIFICATION MADE IN RESPONSE
TO OFFICE ACTION DATED SEPTEMBER 28, 2001**

(Deletions are indicated by double brackets,
while insertions are indicated by underlining)

Page 25, line 11, amend the paragraph to read as follows:

DAGO: H-Tyr-D-Ala-Gly-*N*-MePhe-Gly-ol (μ agonist) [SEQ ID NO:1]

Page 25, line 12, amend the paragraph to read as follows:

DAMME: H-Tyr-D-Ala-Gly-*N*-MePhe-Met(O)-ol (μ agonist) [SEQ ID NO:2]

Page 25, line 15, amend the paragraph to read as follows:

Deltorphin A: [[H-Tyr-D-Ala-Phe-Glu-Val-Val-Gly-NH₂]] H-Try-D-Met-Phe-His-
Leu-Met-NH₂ (δ_1 agonist) [SEQ ID NO:9]

Page 25, line 16, amend the paragraph to read as follows:

Deltorphin B: H-Tyr-D-Ala-Phe-Glu-Val-Val-Gly-NH₂ (δ_2 agonist) [SEQ ID NO:3]

Page 25, line 17, amend the paragraph to read as follows:

DER: dermorphin or H-Tyr-D-Ala-Phe-Gly-Tyr-Pro-Ser-NH₂ (μ agonist) [SEQ ID
NO:4]

Page 25, line 21, amend the paragraph to read as follows:

DPD: H-Dmt-D-Phe-Gly-Val-Val-NH₂ (μ antagonist) [SEQ ID NO:5]

Page 25, line 22, amend the paragraph to read as follows:

DPDPE: H-Tyr-[D-Pen-Gly-Phe-D-Pen] enkephalin (δ_1 agonist) [SEQ ID NO:8]

Page 26, line 23, amend the paragraph to read as follows:

In re Appln. of Lazarus et al.
Application No. 09/814,558

[Trp⁴,Tyr⁵]DER: H-Tyr-D-Ala-Phe-Trp-Tyr-NH₂ (μ agonist) [SEQ ID NO:6]

Page 26, line 24, amend the paragraph to read as follows:

[Trp⁴,Lys-OH⁷]DER: H-Tyr-D-Ala-Phe-Trp-Tyr-Pro-Lys-OH (μ agonist) [SEQ ID
NO:7]



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Filed: March 22, 2001

For: DMT-TIC DI-AND TRI-PEPTIDIC
DERIVATIVES AND RELATED
COMPOSITIONS AND METHODS
OF USE

**AMENDMENTS TO CLAIMS MADE IN RESPONSE
TO OFFICE ACTION DATED SEPTEMBER 28, 2001**

(Insertions are indicated by underlining)

10. (Amended) A composition comprising at least one compound of claim 1 and a
carrier.

20. (Amended) A composition comprising at least one compound of claim 19 and a
carrier.



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Application No. 09/814,558

Art Unit: 1653

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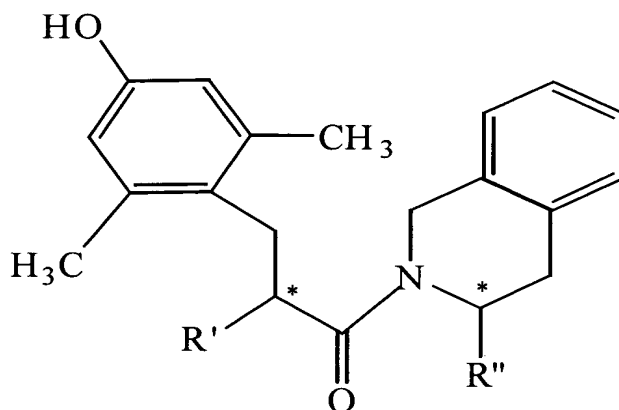
Filed: March 22, 2001

For: DMT-TIC DI-AND TRI-PEPTIDIC
DERIVATIVES AND RELATED
COMPOSITIONS AND METHODS
OF USE

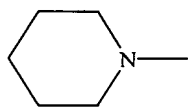
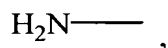
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DATED SEPTEMBER 28, 2001**

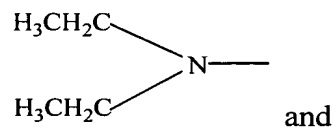
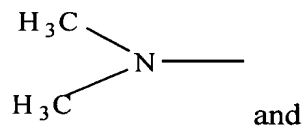
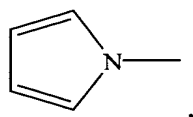
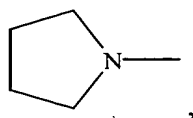
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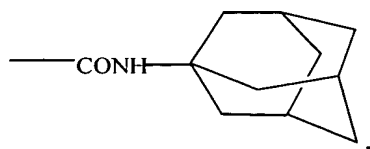
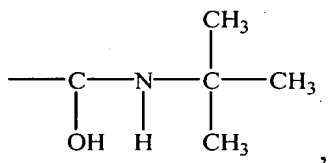
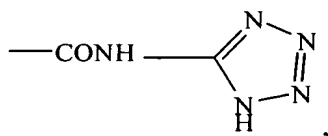
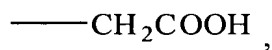


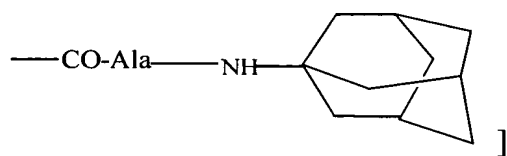
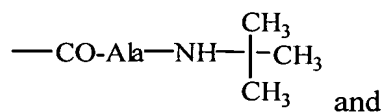
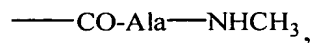
[wherein R' is selected from the group consisting of





R" is selected from the group consisting of





comprising the Dmt-Tic pharmacophore and related compositions and methods of use in the antagonism and agonism of δ and μ opioid receptors and in the inhibition of P-glycoprotein, specifically hMDR-1.